

REMARKS

Upon entry of the above amendments, this application will contain claims 37-41 and 43-52 pending and under consideration. The application was originally filed with claims 1-36. Claims 2-36 were canceled in a Preliminary Amendment. Claim 1 was canceled and claims 37-52 were added in a Second Preliminary Amendment. In the present Response, claims 37, 40, and 43 have been amended, and claim 42 has been canceled.

For the reasons discussed more fully below, it is believed that the pending claims are patentable over the cited references, and therefore, withdrawal of all outstanding rejections is respectfully requested.

Objections to the Disclosure

The Applicants have submitted an amendment to the specification to include a cross-reference to related applications. It is believed that this amendment overcomes the Examiner's objection to the specification.

Rejections Under 35 USC §112

Claims 37 through 46 were rejected under 35 USC §112, second paragraph. It was alleged that "with respect to base claim 37, lines 8 and 9, 'the tissue membrane,' an unpatentable part of the human body, is positively recited as a structural part of the invention." The Applicants respectfully disagree with the Examiner's interpretation of the text quoted from the claim. The tissue membrane is included in the claim to further define the structural elements, i.e., the needle, recited in the claim. However, to further the prosecution of the present application, claim 37 has been amended to recite that wherein "the needle is configured to carry at least a portion of a length of suture". It is believed that this amendment of claim 37 overcomes the rejection. Independent claim 43 has been similarly amended.

It is believed that these amendments overcome the Examiner's rejection. Therefore, withdrawal of the rejections of claims 37-46 is respectfully requested.

Rejections Under 35 USC §102

Claims 37-41 and 43-45 were rejected under 35 USC §102(b) over Casillo (US 4,107,953). The Examiner indicated that none of the prior art of record, alone or in combination, discloses an apparatus for suturing a tissue member with inter alia, a tubular body, a needle, and a hemostasis seal member, where the apparatus includes a suture retrieval assembly and where the needle has an eyelet and a double-back length of suture. (Office Action, page 6.)

Independent claim 37 has been amended substantially as suggested by the Examiner in the Office Action. Claim 37 now includes a tubular body, a needle, a hemostasis seal member, a suture retrieval assembly, and where the needle has an eyelet.

Consequently, claim 40 has been amended to recite that the needle carries a double-back length of suture, and claim 42 has been canceled. It is believed that the amendment of claim 37 overcomes the rejection of claims 37-41. Therefore, withdrawal of these rejections is requested.

Independent claim 43 has been amended to recite that the distal portion of the tubular body is sized to be extendable through an opening in the tissue membrane caused by a catheterization procedure. It is respectfully submitted that this amendment overcomes the rejection of claim 43 over Casillo.

Casillo describes a semi-automatic crocheting tool as illustrated in Figures 1-8. The distal tubular body 12, as identified in the Office Action, is integral with the chassis (also listed as reference number 12) which includes a ratchet gear 62, pawl 66 to control ratchet gear 62, and dial 68 which are provided to count the number of selective engagements and retractions of the needle. (Casillo, col. 3, line 50 through col. 4, line 24.) It is submitted that this chassis 12 on the distal end of the tube cannot be of a size to be extended through a tissue membrane caused by a catheterization procedure. Catheterization procedures are typically performed on a veins and arteries, which have small diameters. The semi-automatic crocheting tool illustrated in Casillo could not be inserted through such a tissue membrane. Consequently, it is believed that claim 43, as amended, is patentably distinct over Casillo. Therefore, withdrawal of the rejections of claims 43-45 is respectfully requested.

Claims 37, 42, 43, 46-48, 50, and 52 were rejected over Lee (US 5,292,332). Claim 37 has been amended as noted above. It is believed that this amendment also overcomes the rejection over Lee.

Claim 42 has been canceled. Consequently, this rejection is moot.

Regarding the remaining rejections of claims 43, 46-48, 50, and 52, the Applicants respectfully disagree with the Examiner's characterization of Lee's apparatus. The apparatus disclosed in Lee is a device for sealing arterial puncture sites with a screw-plug. Consequently, this device does not carry a length of suture as presently claimed. The device does carry a guide wire 18. Guide wire 18 serves to direct and position the delivery catheter 34 and screw-plug 22 into the opening in the artery. However, guide wire 18 is not a suture nor can it be used for a suture. Furthermore, Lee's device also does not contain a hollow needle advanceable in a distal direction along a tubular body as recited in the independent claims 43 and 47. The Examiner also identified tube 38 as a needle. However, tube 38 is not a needle carrying a suture material; rather, tube 38 is just as it is indicated--a hollow tube through which the guide wire extends. Tube 38 is not extendable through a tubular body nor is the tubular body extendable through the tissue membrane adjacent an opening in the tissue membrane. As noted above, the guide wire 18 serves merely to direct the remaining components into the puncture site. Therefore, tube 38 and hollow tube 34 must follow the guide wire through the opening in the arterial wall--not through the tissue adjacent the opening of the arterial wall as recited in the claims. There is no description or suggestion of a needle that could puncture tissue adjacent the opening in the arterial wall, and consequently, no suture can be inserted through the tissue, either. It is believed that claim 43 is patentably distinct from the cited reference. Therefore, withdrawal of the rejections of claim 43 and 46 is requested.

Independent claim 47 also includes the needle advanceable in a distal direction along the tubular body and through the tissue membrane adjacent the opening in the tissue membrane. For the reasons discussed above, it is believed that claim 47 is patentably distinct from Lee. Therefore, withdrawal of the rejections of claims 47, 48, 50, and 52 is respectfully requested.

#### Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the cited references, either singly, or in combination, do not disclose or make obvious the claimed invention. Accordingly, reconsideration leading to withdraw of all the rejections under 35 U.S.C. §§112 and 102 and passage of this application containing claims 37-41 and 43-52 are respectfully

requested. Additionally, the Examiner is invited to telephone the undersigned attorney if there are any questions about this submission or other matters, which may be addressed in that fashion.

Respectfully submitted,

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